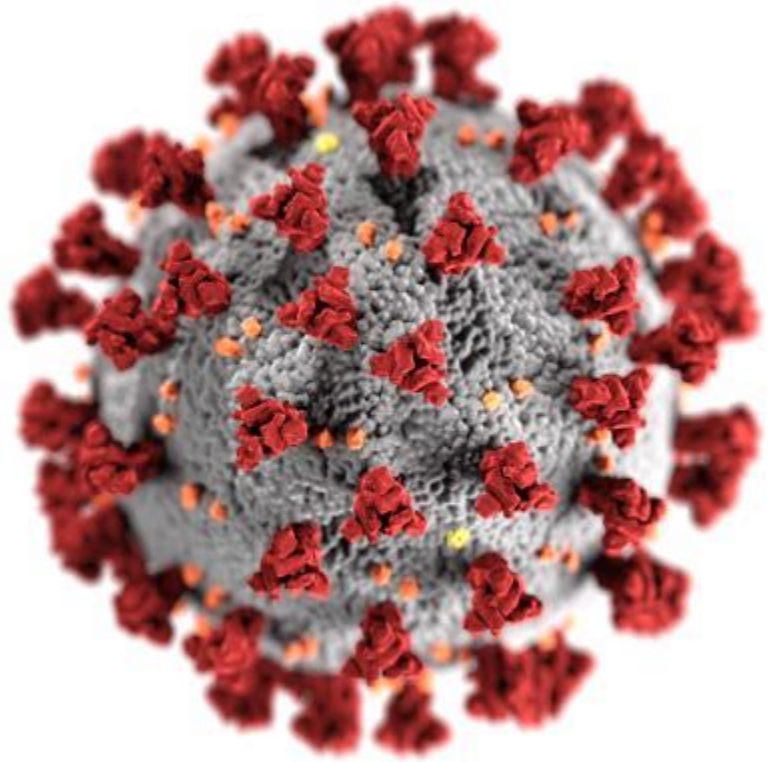
COVID-19 Vaccination Plan

South Dakota Department of Health

October 27, 2020



We will begin in just a few moments. Thanks!

Information is current as of 10.27.2020

SOUTH DAKOTA DEPARTMENT OF HEALTH

Agenda

- COVID 19 Vaccines
- Vaccination Presentations
- SD COVID Vaccination Plan
- Vaccination Phases
- Vaccine storage and handling
- Provider Enrollment
- Documentation of COVID Vaccination
- Q&A

Information is current as of 10.27.2020

SOUTH DAKOTA DEPARTMENT OF HEALTH

COVID 19 Vaccines/Phase 3

Pfizer	mRNA Vaccine
Moderna	mRNA Vaccine
AstraZeneca	vector (adenovirus) Vaccine
Johnson & Johnson	recombinant vector (adenovirus) vaccine

OWS/CDC contracted with 6 manufacturers to produce 800 million doses

Vaccination Presentations

- Early doses of vaccine will be in multi dose vials
- There will be variable vaccine storage requirements --70C, -20C, 2-8C
- Stability testing is still being conducted and storage requirements and expiration dates may change
- May be other presentations of vaccine available later: SDV, SDS

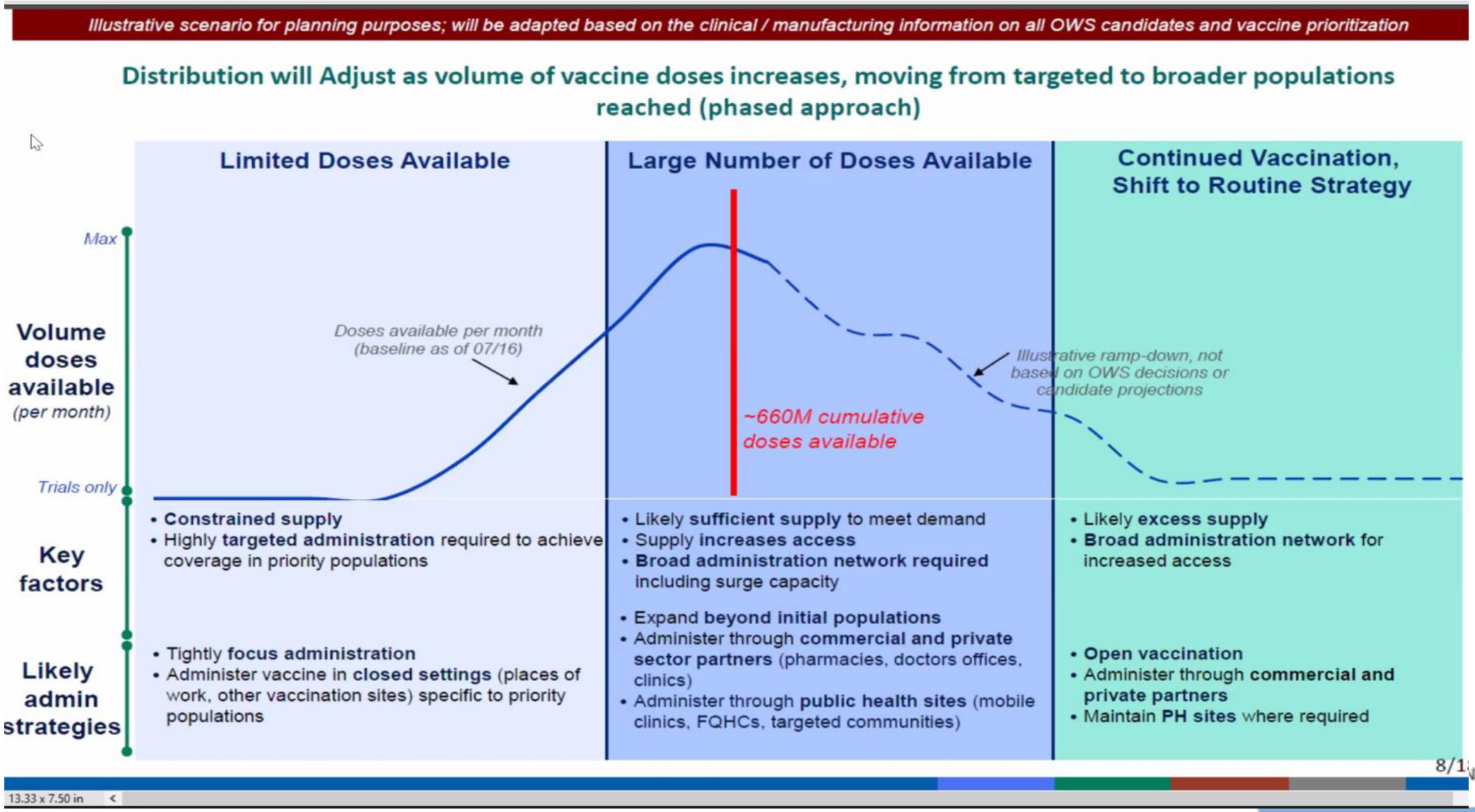
SD COVID Vaccination Plan

Section 1: COVID-19 Vaccination Preparedness Planning
Section 2: COVID-19 Organizational Structure and Partner Involvement
Section 3: Phased Approach to COVID-19 Vaccination
Section 4: Critical Populations
Section 5: COVID-19 Provider Recruitment and Enrollment
Section 6: COVID-19 Vaccine Administration Capacity
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management
Section 8: COVID-19 Vaccine Storage and Handling
Section 9: COVID-19 Vaccine Administration Documentation and Reporting
Section 10: COVID-19 Vaccination Second-Dose Reminders
Section 11: COVID-19 Requirements for IISs or Other External Systems
Section 12: COVID-19 Vaccination Program Communication
Section 13: Regulatory Considerations for COVID-19 Vaccination
Section 14: COVID-19 Vaccine Safety Monitoring
Section 15: COVID-19 Vaccination Program Monitoring

Target Populations for phase 1

- Healthcare personnel
- Other essential workers
- LTC Residents and staff
- Underlying medical conditions
- Persons 65 and older
- Persons from racial and ethnic minority groups
- Persons from Tribal communities
- Persons incarcerated
- Homeless shelters
- Colleges and Universities
- Persons living or working in congregate settings
- Rural communities
- Persons with disabilities
- Un/underinsured

Vaccination Phases



Vaccine storage and handling

- Imperative to maintain appropriate temperatures
- Temperatures monitored with a digital data logger
- Temperatures recorded twice daily
- Details on working through a temperature excursion are forthcoming

Vaccine storage and handling

Vaccine availability under EUA by			
Candidate	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine A	10M–20M doses	20M–30M doses	Ultra-cold (-75 °C) storage requirements, for large sites only

SHIPMENT

3 separately acquired components (mixed on site)

1. Vaccine
   - 2mL vial, Multidose vials (5 doses/vial)
   - Direct to site from manufacturer (on dry ice) in thermal shipping container
   - Thermal shipping container estimated specs: 400mm X 400mm X 560mm
2. Diluent and ancillary supply kits (for administration and mixing)
   - Direct to site from the US Government (USG) at room temperature)
3. Thermal shipping container should be returned once use is completed. Instructions for mail back and labels will be forthcoming.

ON-SITE VACCINE STORAGE

Ultra-Low Temp Frozen (-90°C to -60°C)

- Freezer units capable of ultra-cold temperatures (UCT)
- The shipping container (thermal shipper) may be used to store vaccines:
  - Once received, thermal shipping container should be replenished with pelleted dry ice within 24 hours
  - Containers may only be opened two times a day.
  - Containers should be replenished with dry ice every 5 days to maintain required temperature.
  - Total amount of dry ice needed per thermal shipper 'recharge' is ~23kg.
  - Container may be recharged up to 3 times (once upon receipt, and two more time there after)
- Temperature Monitoring needs to happen in alignment with CDC guidance, irrespective of re-icing
  - Thermal shipping container may be monitored using temperature probes on the container, in alignment with guidance provided by CDC and information provided by the manufacturer.
  - Direct handling of dry ice needed for recharging the containers will require the use of appropriate PPE

Vaccine storage and handling

	Thawed but NOT diluted (2–8 °C) • Product may be removed from the ULT or thermal shipping container and thawed and stored at 2—8°C for up to 5 days (discard unused doses after 5 days) • Cannot return to UCT storage or thermal shipper once thawed ***Diluted (room temperature)*** • If removed directly from UCT, vaccine must be thawed ~30minutes at room temperature before dilution. • Once vaccine is at room temperature, it must be diluted within 2 hours. • Must use diluted vaccine within 6 hours (discard any unused, diluted vaccine after 6 hours)
ORDERS ***Large quantities, to large administration sites only*** • Minimum order: ~1,000 doses • Maximum order: ~5,000 doses	**ADMINISTRATION** ***2-dose series (21 days between doses)*** • On-site mixing required; dilute with diluent just prior to administration; all 5 doses must be administered within 6 hours of dilution; remainder of diluted vaccine should be discarded. • Multidose vial contains 5 doses • Administer by intramuscular (IM) injection
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES ***NOTE: primary administration sites may consider providing vials to other sites HOWEVER all cold chain should be maintained and logged in accordance with the information provided above.*** ***Healthcare personnel*** — public health, closed point of dispensing (POD), temporary/off-site vaccination clinics + potential for mobile clinics ***Other essential workers*** — public health, closed POD, temporary/off-site vaccination clinics + potential for mobile clinics ***Adults with underlying medical conditions and people 65 years of age and older*** — open PODs in strategic locations, potential for mobile clinics to long-term care facilities or partnership with pharmacy onsite clinics for LTCFs, correctional/detention facilities, and other congregate settings	

Vaccine storage and handling

Vaccine availability under EUA by				
Candidate	**End of Oct 2020**	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine B	~1M doses	~10M doses	~15M doses	Central distributor capacity required (-20 °C)

Vaccine B

SHIPMENT

2 separately shipped components

1. Vaccine
   - To central distributor (at -20 °C)
   - Multidose vials (10 doses/vial)
2. Ancillary supply kits
   - Direct to site from USG (at room temperature)

ON-SITE VACCINE STORAGE

Frozen (-20 °C)

- Storage in shipping container OK

Refrigerated (2–8 °C)

- Must use within 14 days

Room temperature

- Must use within 6 hours (discard any unused vaccine after 6 hours)

ORDERS

Central distribution capacity required

- Required by Dec 2020
- Maintained at -20 °C

ADMINISTRATION

2-dose series (28 days between doses)

- No on-site mixing required
- Administer by IM injection

INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES

Healthcare personnel — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics

Other essential workers (specifics TBA) —occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics

People at higher risk of severe COVID-19 illness (e.g., LTCF residents) — commercial pharmacy partners + mobile clinics

As of 10-26-2020

Product Packaging Overview

1 Primary Packaging

- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

2 Secondary Packaging "Single Tray"

- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

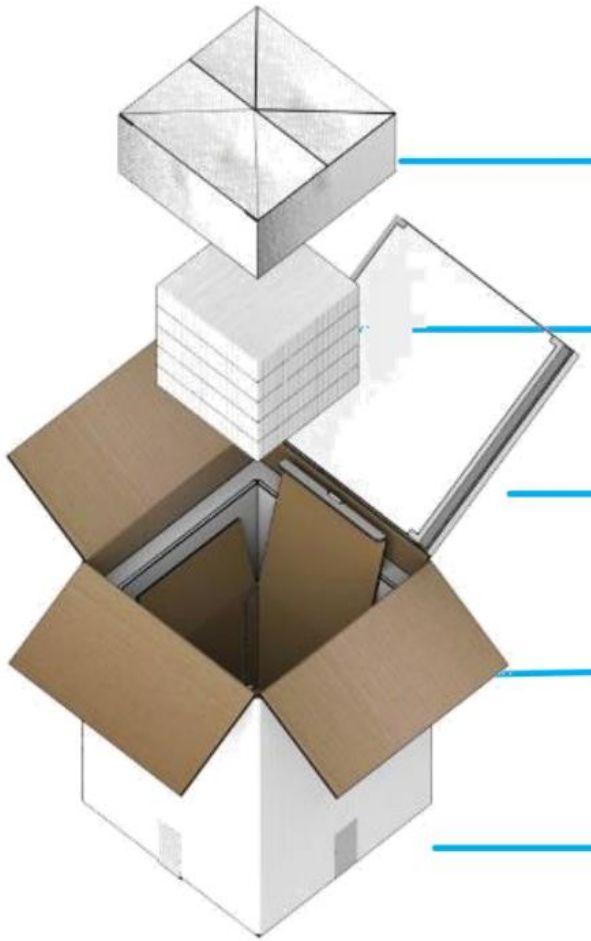
3 Tertiary Container: Thermal Shipper

Item	Description
1	Dry Ice Pod
2	Payload (Vial Trays)
3	Inner Lid
4	Payload Sleeve
5	Outer Carton

- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT (-75±15°C) up to 10 days if stored at 15°C to 25°C temperatures without opening.
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice

Please see slide 2 for important limitations with respect to this presentation.

Ultra Low Temperature Thermal Shipper – Overview of Pack Out



ITEM	DESCRIPTION
1	DRY ICE POD
2	PAYLOAD (VIAL TRAYS)
3	INNER LID
4	PAYLOAD SLEEVE
5	OUTER CARTON

Weights and Dimensions	
Tare Weight (Inc. Dry-Ice)	8.5kg (31.5kg)
Volumetric Weight	15.0kg
Payload Space L x W x H	245x245x241mm
Shipper Dimensions L x W x H	400x400x560mm

Please see slide 2 for important limitations with respect to this presentation.


PfizerThermalShipper_9_23
Proprietary, scaffold design
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Vaccine Storage Options* At the Point of Vaccination

1 Ultra-Low Temperature Freezer

- Store as frozen liquid at -75°C±15°C for long term storage.
  - Emergency Use vials are labeled as -70°C±10°C, however they can be safely stored in a freezer set to the USP condition of -75°C±15°C
- Frozen vials at have a 6 month expiry from the date of manufacture
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)

2 Thermal Shipper Designed for Temporary Storage

- Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Local dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper should be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
- Apply appropriate dry ice temperature monitor

3 2 to 8°C Refrigerator

- Can be stored at 2 to 8°C up to 5 days
- Room temperature storage is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current understanding based on the totality of available data currently. Current as of September 8, 2020.

Pfizer | BIONTECH

Please see slide 2 for important limitations with respect to this presentation.

Provider Enrollment

- **Qualtrics** platform is being used for enrollment https://dohsd.sjc1.qualtrics.com/jfe/form/SV_eVYZ1lht9aCoHFX
- Provider Agreement
- Provider Profile
- Assigning of Unique Provider COVID Vaccine Number

Documentation of COVID Vaccination

- **SDIIS** is preferred method of documentation
- Can use EMR if an HL7 connection is established to SDIIS
- Vaccines must be documented within 24 hours of administration
- Inventory is reported to **vaccinefinder.org** daily – more info to come

Contact Information

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